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09/857,995	10/05/2001	John P. McKearn	CU-2560 RJS	4037

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EXAMINER

PATEL, SUDHAKER B

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,995

Applicant(s)

J.P. McKearn et al

Examiner

Sudhaker Patel

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— The MAILING DATE of this communication appears on the cover sheet with the corresponding address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 3, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-106 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-106 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

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DETAILED ACTION

Applicant's communication paper # 9 dated 4/3/01 is acknowledged.

Applicants' election of Group VIII and the species of compound # 11 thiomorpholine as chemical structure/molecule of claim 29 can not be grouped with compounds of Group VIII which have only pyridine as heterocycle. Therefore, restriction is regrouped in the following way.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

The Matrix Metalloproteinase(*MMP*) *inhibitors* themselves can be grouped in the following way, each group having different chemical structure:

MMP Group A). Having core as : **Sulfone:** *Heterocycle C-SO₂-C-Non-heterocycle* i.e. compounds # 1,2,6,7,8,14,15,16,17,18,20.

MMP Group B). Having core as: **Sulfonamide:** *Heterocycle C-SO₂-N Heterocycle* i.e. compounds # 3,4 of claim 29.

MMP Group C). Having core as: **Sulfonamide:** *Non-heterocycle C-SO₂-N Heterocycle* i.e. compound #5 of claim 29.

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MMP Group D). Having core as: *Non-heterocycle and non-aryl hydroxy amine-CO—
--CO-NH-CH3* i.e. compound 9 of claim 29

MMP Group E). Having core as: *Non-heterocyclic aryl acid* i.e. compound # 10 of
claim 29.

MMP Group F). Having core as: *6-membered Heterocycle with 2 heteroatoms of which
one atom is N-SO2-C nonheterocycle* i.e. compound # 11 of claim 29

MMP Group G). Having core as : *Substituted amino tetracycline* i.e. compound # 12 of
claim 29.

MMP Group H). Having core as: *Substituted imidazole* i.e. Chiroscience D-2163
compound # 13 of claim 29.

MMP Group I). Having core as: *6-membered heterocycle pyran C-SO2-C
nonheterocycle* i.e. compounds # 19,23,24 of claim 29.

MMP Group J). Having core as: *Heterocycle C-SO2-C nonheterocycle diphenyl sulfide*
i.e. compounds # 21,22 of claim 29.

The inventions are grouped as follows:

Group I, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a
method use, and method of making composition wherein MMP inhibitors are of above
mentioned Group F). Compound # 11 of claim 29 having **thiomorpholine** molecule in the
structure, classified in class 544, subclass-58.2, class-514-subclass 227.8, and Irinotecan or
Topotecan together with radiation for treatment of neoplasia.

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Group II, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of bellow mentioned Group A)., and they have the generic core : “ *Heterocycle C-SO₂-C-nonheterocycle*” Compounds # 1,2,6,7,8,14,15,16,17,18,20 of claim 29 having **pyridine molecule** in the structure, classified in class **546**, subclasses various depending on the nature of variables, and Irinotecan or Topotecan together with radiation for treatment of neoplasia.

Group III, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors having **6 membered heterocycle with O** as heteroatom similar to **MMP Group I**. Having core as: *6-membered heterocycle pyran C-SO₂-C nonheterocycle* i.e. compounds # 19,23,24 of claim 29, classified in class **549**, subclasses various depending on the nature of variables, and Irinotecan or Topotecan together with radiation for treatment of neoplasia.

Group IV, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a method use, and method of making composition wherein **MMP Group D**. Having core as: *Non-heterocycle and non-aryl hydroxy amine-CO-----CO-NH-CH₃* i.e. compound 9 of claim 29 involving **non-heterocyclic chemistry**, classified in classes **560,562,564**, subclasses various depending on the nature of variables, and Irinotecan or Topotecan together with radiation for treatment of neoplasia.

Group V, claim(s)(in part) 1-3,28-46,71-102, 11,21,54,64 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of other MMP

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groups not cited in above groups I-IV, and antineoplastic agents. If this group is elected further restriction/election will be requires as there are many unknowns. Additionally, a single species by way of an example with specifics for all variables must be disclosed.

Group VI, claims (in part) 1-106 drawn to simple compositions, a method use, and method of making composition wherein MMP inhibitors are of claim 29, and the antineoplastic agents are of claims 4-20,22-27. If this group is elected further restriction/election will be requires as there are many unknowns. Additionally, a single species by way of an example with specifics for all variables must be disclosed.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They represent different combinations of chemical structures with different substituents which constitute the make up of the composition for treatment.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. A telephone call was made to Mr.Streit/Mr.W.Dennis on 4/18/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr.Mukund Shah can be reached at (703) 308 4716.

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A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Mukund J. Shah
MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1600

Sp/April 18, 2002.